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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,970	12/13/2001	Marcus B. Gohlke	068349-01/20	4120

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R. William Beard, Jr.  
Baker Botts L.L.P.  
910 Louisiana Street  
Houston, TX 77002-4995

EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1684

DATE MAILED 10/21/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/021,970

Examiner

Susan Coe

Applicant(s)

GOHLKE, MARCUS B.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

1) ☐ Notice of Reference Cited (PTO-891)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No. 1-3

4) ☐ Interview Summary (PTO-914) Paper No. 1-3

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other

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### **DETAILED ACTION**

1. The amendment filed August 7, 2002, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. The declaration of Marcus Gohlke, submitted August 7, 2002, has been considered.
3. Claims 19-24 have been cancelled.
4. Claims 1-18 are pending.

### ***Priority***

Applicant's have claimed domestic priority as a CIP of Application No. 09/778,294 which is a divisional of Application No. 09/370,654. These applications do not support a combination of beta-glucan and lactoferrin. Therefore, claims drawn to this composition are not granted a priority date based on these applications.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 4-6, and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,352,698 B1.

Applicant's claims are drawn to a composition comprising lactoferrin and beta-glucan.

US '698 teaches a composition that comprises lactoferrin and beta-glucan. The composition can contain numerous additional ingredients that are considered to meet the limitations of applicant's claims 12-14 (see claims). The beta-glucan is from yeast (see column 3, lines 66-67). The composition is in numerous liquid forms (see column 6, lines 27-32).

5. Claims 1, 2, 4, 5, and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,406,897 B1.

US '897 teaches a composition that contains beta-glucan and lactoferrin. The composition can be in solid or liquid forms (see claims). The composition can contain numerous additional ingredients that are considered to meet the limitations of applicant's claims 12-14 (see Formulation Examples). The glucan can be from mushrooms (see column 2, lines 38-42).

#### *Claim Rejections - 35 USC § 103*

6. Claims 1, 5, 7-11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,352,698 B1.

As discussed above, US '698 is considered to teach a composition of lactoferrin, beta-

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amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach that the beta-glucan is from oat or mushrooms. However, these are known sources of beta-glucan. A person of ordinary skill in the art would expect that beta-glucan from these sources would be suitable for use in the composition taught by the reference based on the fact that the same substance can be obtained from these sources. Thus, an artisan of ordinary would be motivated to use beta-glucan from oat or mushrooms in the composition of the prior art.

The reference also does not specifically teach that the lactoferrin is mammalian or from bovine milk. However, these are known sources of lactoferrin. A person of ordinary skill in the art would expect that lactoferrin from these sources would be suitable for use in the composition taught by the reference based on the fact that the same substance can be obtained from these sources. Thus, an artisan of ordinary would be motivated to use lactoferrin from mammals or bovines in the composition of the prior art.

7. Claims 1, 5-11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable

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As discussed above, US '897 is considered to teach a composition of lactoferrin, beta-glucan, and nutritionally acceptable carriers, diluents, and flavorings. However, the reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach that the beta-glucan is from oat or yeast. However, these are known sources of beta-glucan. A person of ordinary skill in the art would expect that beta-glucan from these sources would be suitable for use in the composition taught by the reference based on the fact that the same substance can be obtained from these sources. Thus, an artisan of ordinary would be motivated to use beta-glucan from oat or yeast in the composition of the prior art.

The reference also does not specifically teach that the lactoferrin is mammalian or from bovine milk. However, these are known sources of lactoferrin. A person of ordinary skill in the art would expect that lactoferrin from these sources would be suitable for use in the composition taught by the reference based on the fact that the same substance can be obtained from these

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8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,296,464, US Pat. No. 5,783,569, and US Pat. No. 5,670,138 for the reasons set forth on pages 4-6 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the combination of lactoferrin and beta-glucan produces unexpected results. The declaration Marcus Gohlke states that the composition has unexpected results because the combination of the two ingredients balances the negative side effects of each while not cancelling out the beneficial effects of each ingredient. Applicant has submitted references detailing the properties of each ingredient. Based on the information in these references and the statements made by applicant, it does not appear that the composition produces unexpected results. It seems that each ingredient is functioning in a manner that would be expected based on the known properties of each the compounds. The fact that some of the properties balance each other out is also not unexpected since the ingredients are known to have somewhat opposite effects on the body. Please note that MPEP section 716.02(c) states "Expected beneficial results are evidence of obviousness of a claimed invention...". The benefits of the combination of lactoferrin and beta-glucan are not unexpected based on what was known in the art at the time of the invention. Therefore, applicant's claim of unexpected results is not persuasive.

9. No claims are allowed.

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examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC  
October 8, 2002



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER